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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,890	11/20/2000	David N. S. Hon	460-001 Cont.IV	5003
1009	7590	01/28/2003	EXAMINER	
KING & SCHICKLI, PLLC 247 NORTH BROADWAY LEXINGTON, KY 40507			PATTEN, PATRICIA A	
ART UNIT	PAPER NUMBER			
1654		//		
DATE MAILED: 01/28/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/716,890

Applicant(s)

Hon et al.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Nov 18, 2002

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 28-31 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 28-31 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). 9

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-27 were cancelled in Paper No.10.

Claims 28-31 are pending in the application.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 37-43 added in Preliminary Amendment A (Paper No. 5) have been renumbered 22-28. It is noted that the Attorney was contacted with regard to this matter (Please see copy of Interview summary, Paper No. 9).

Changes were made accordingly in the 'Remarks' section of Amendment A to coincide with the corrected claim numbers.

Claims 28-31 are pending in the application and were presented for examination on the merits.

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***Election/Restriction***

Applicant's election of Group VII, Claim 28 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The non-elected claims were cancelled in Paper No. 10.

Claims 28-31 have been presented for examination on the merits.

***Trademarks***

The use of the trademark WHITFIELD'S and BENCELOK has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28 and 30-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,149,947. An obviousness-type double patenting rejection is appropriate where

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the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Specifically, claim 28 recites 'a method for enhancing wound healing at a site via modulation of matrix metalloproteinase activity at the wound site' by administration of a composition comprising a carrier and particular parts by weight of ions. Claim 5 of '947 also recites the same composition in the method claim. It is noted that there are 4 differences between Instant claim 28 and claim 5 of '947:

- 1) While claim 5 of '947 recites 'a method for *treating a skin lesion* comprising applying *to the lesion....*', Instant claim 28 recites a 'method for *enhancing wound* healing at a site via modulation of matrix metalloproteinase activity *at the wound site*'. Because a skin lesion is a wound, the recitation of 'skin lesion' in claim 5 of '947 anticipates 'wound'.

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2) While claim 5 of '947 recites 'treating', Instant claim 28 recites 'enhancing wound healing'. It is deemed that 'treating' and 'enhancing wound healing' are substantially the same scope since 'treating' a skin lesion or wound would incorporate enhancement of healing, especially considering '947 teaches that both the oak bark extract and the synthetic mixture 'function to enhance wound healing' (col. 4, lines 6-9). Thus, one of ordinary skill in the art would have reasonably concluded that the method would have been useful in enhancing wound healing based upon the teachings of '947 and therefore the recitation of 'enhance wound healing' is obvious over '947.

3) Claim 5 of '947 recites 'said parts by weight being expressed as parts by weight of inorganic solids', while Instant claim 28 does not recite this language at the end of the claim. Although claim 28 did not specifically recite this language, it is clear from the Instant specification that the synthetic formulation which contains the claimed parts by weight of ions were expressed as parts by weight of inorganic solids (p.3, lines 7-8). Thus, the Instant specification has taught that the parts recited with regard to ions in the synthetic mixture were recited by weight of inorganic solids. The Examiner has deemed that the parts of ions in the synthetic mixture *have thus been defined* as being expressed by weight of inorganic solids. Therefore, this embodiment of the claim is anticipated by claim 5 of '947.

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4) Instant claim 28 recites '...via modulation of a matrix metalloproteinase activity', wherein claim 5 of '947 does not recite this property. This phrase is considered an inherent property of the method which is not critical to the patentability of the claim. If one practiced the method as described in claim 5 of '947, the mechanism of action would inherently take place as a consequence of practicing the method, since claim 5 of '947 comprises applying the same composition as disclosed in Instant claim 28 to the site of the lesion, especially lacking sufficient evidence to the contrary. Thus, it is deemed that this property is anticipated by claim 5 of '947 as it is an inherent property.

Claims 30-31 recite wherein the carrier is water and wherein the carrier is cream based, respectively (with regard to the composition found in claim 28). Although claim 5 of '947 did not specifically recite wherein the carrier was water or cream based, '947 clearly suggested the incorporation of water or a cream base as the carrier for the synthetic mixture (col.2, lines 45-47). Thus, one of ordinary skill in the art would have been motivated to have incorporated water or a cream base as the carrier for the composition of claim 28 since these types of carriers were disclosed by '947 as being advantageously added to the composition to form the therapeutic composition.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 28 recites ‘...via modulation of a matrix metalloproteinase activity’. While the Instant specification teaches that the mode of action of the Oak bark extract as well as the synthetic mixture of inorganic solids may inhibit some proteinases such as carboxypeptidase (p.7, lines 7-19) there is no teaching wherein performing the method modulates matrix metalloproteinase. Applicants state that they are not intending to be bound by any particular mechanism of action (p.7, lines 7-8) but suggest that the synthetic composition as well as the Oak bark extract ‘interact’ with the listed enzymes. The ‘matrix metalloproteinase’ is distinct from any of the enzymes listed on page 7 of the Instant specification with regard to structure and function. Thus, the recitation of ‘matrix metalloproteinase’ does not flow freely from the specification as originally filed,

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and one would not reasonably conclude that a matrix metalloproteinase would be an obvious substitute for any of the proteinases disclosed in the Instant specification especially lacking information with regard to the biochemical mechanisms of the composition. Although the enzyme may be known to be present during wound repair, Applicants did not initially disclose this information in the Instant specification nor any of the previous applications. Therefore, this phrase as Instantly recited is deemed New Matter. Because claims 29-31 depend upon claim 28, it is deemed that these claims also contain New Matter because all of the limitations of claim 28 are present in claims 29-31.

It is noted that Applicants have filed this application as a Continuation. Applicants may wish to convert this application into a Continuation In Part (CIP) of the previous application which would overcome this New Matter rejection. Applicants are reminded that upon conversion, a new updated Oath will be in order. Alternatively, deletion of the New Matter will overcome this rejection.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 29 is drawn to wherein the composition of claim 28 comprises from 40% to 80% by weight of solids of an aqueous oak bark extract. Although there is confusion regarding this claim (Please see rejection under 35 U.S.C. 112 Second paragraph *infra*), the claim has been interpreted to mean that the composition of claim 28 *is* a 40-80% oak bark extract.

There is no indication within the Instant specification that an aqueous extract of oak bark (40-80%) would coincide with the parts by weight of ions as recited in claim 28. On the contrary, Table 2 describes the concentrations in ppm of individual elements up to 40%. Even assuming that the parts in Claim 28 were drawn to parts per million (ppm) (claim 28 is actually drawn to parts by weight of inorganic solids), calculations of the individual elements at 40% concentration (Table 2) conclude that they do not coincide with the parts as recited in claim 2 in parts per million. Further, the Examiner cannot extrapolate to 80% concentration of the oak bark extract to determine the ppm of the ions in the extract because the data points are not linear, and some points are outliers (please see Appendix A attached hereto).

Thus, although it is clearly disclosed that the particular ranges of ions were produced synthetically by Applicants, it does not appear that Applicants were in

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possession of an extract of oak bark which actually possessed the claimed ranges of ions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites 'wherein the composition comprises from 40% to 80% by weight of solids of an aqueous oak bark extract'. This phrase is confusing in that it is not known if Applicants intend for this to mean that the recited composition in claim 28 further comprises the solids from an aqueous oak bark extract, or wherein the composition as recited in claim 28 *is* an oak bark extract. If Applicants intend for this to mean that the composition as recited in claim 28 is an extract of oak bark, it is suggested that the claim be reworded to read:

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'The method of claim 28, wherein the active ingredient of organic solids is extracted from oak bark' for example.

Claims are free of the art. The closest prior art of record is Stanley (US 5,080,900). Stanley disclosed a method for extracting the ash of oak bark. However, Stanley did not disclose the particular inorganic solids or ions, or the particular ranges of ions by weight of inorganic solids as instantly claimed. The particular ranges of ions by weight of inorganic solids are clearly drawn to the embodiment within the specification which teaches a synthetic mixture of these ions. Therefore, it is not known if the particularly claimed ranges of ions could be prepared via extraction of oak bark.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

January 22, 2003

A handwritten signature in black ink, appearing to read "Patricia Patten". The signature is fluid and cursive, with a large, stylized "P" at the beginning.

Patricia Patten